

0-16-03



CASE N-32663A/USN

FILING BY "EXPRESS MAIL" UNDER 37 CFR 1.10

EL 987586878 US  
Express Mail Label Number

OCTOBER 15, 2003  
Date of Deposit

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF

TROUP ET AL.

APPLICATION NO: 10/662,678

FILED: SEPTEMBER 15, 2003

FOR: NUTRITIONAL COMPOSITIONS

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Sir:

This paper is being filed within three months of the filing date of the application. Therefore, no fees are required. If a fee is deemed to be required, the Commissioner is hereby authorized to charge such fee to Deposit Account No. 19-0134.

In accordance with 37 C.F.R. §1.56, applicants wish to call the Examiner's attention to the references cited on the attached form(s) PTO-1449.

Copies of these references are enclosed herewith.



01-13-04

CASE N-32663A/USN

FILING BY "EXPRESS MAIL" UNDER 37 CFR 1.10

EV 336721087 US

Express Mail Label Number

January 12, 2004

Date of Deposit

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF

Art Unit: ~~1701~~ 1654

TROUP ET AL.

APPLICATION NO: 10/662,678

FILED: SEPTEMBER 15, 2003

FOR: NUTRITIONAL COMPOSITIONS

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Sir:

This paper is supplemental to the Information Disclosure Statement filed October 15, 2003. Since Applicants believe this paper is being filed before the mailing date of a first Office Action on the merits, no fees are believed to be required under 37 C.F.R. §1.97(b)(3). If a fee is deemed to be required, the Commissioner is hereby authorized to charge such fee to Deposit Account No. 19-0134.


In accordance with 37 C.F.R. §1.56, applicants wish to call the Examiner's attention to the references cited on the attached form(s) PTO-1449.

Copies of these references are enclosed herewith.

The Examiner is requested to consider the foregoing information in relation to this application and indicate that each reference was considered by returning a copy of the initialed PTO 1449 form(s).

Respectfully submitted,

Novartis  
Corporate Intellectual Property  
One Health Plaza, Building 430  
East Hanover, NJ 07936-1080  
(862) 778-7877

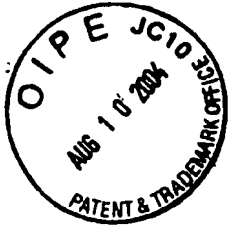
  
John W. Kung  
Attorney for Applicants  
Reg. No. 44,199

Date: 1/12/2004

08-11-04

1701

CASE N-32663A



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|---|---|
| FILING BY "EXPRESS MAIL" UNDER 37 CFR 1.10          |   |
| <u>EV 540156906 US</u><br>Express Mail Label Number | <u>August 10, 2004</u><br>Date of Deposit |

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF

Art Unit: ~~1701~~ 1634

TROUP ET AL.

APPLICATION NO: 10/662,678

FILED: SEPTEMBER 15, 2003

FOR: NUTRITIONAL COMPOSITIONS

**MS: Amendment**  
Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

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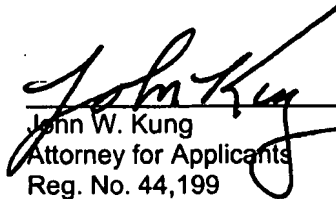
In accordance with 37 C.F.R. §1.56, applicants wish to call the Examiner's attention to the references cited on the attached form(s) PTO-1449.

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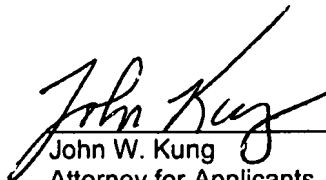
  
John W. Kung  
Attorney for Applicants  
Reg. No. 44,199

Date: *August 10, 2004*

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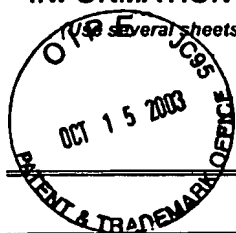
  
\_\_\_\_\_  
John W. Kung  
Attorney for Applicants  
Reg. No. 44,199

Date: *October 15, 2003*

## INFORMATION DISCLOSURE CITATION

ATTY. DOCKET NO.  
N-32663A  
APPLICATION NO.  
Not Yet Assigned  
APPLICANT  
TROUP ET AL.  
FILING DATE  
September 15, 2003

Group



## U.S. PATENT DOCUMENTS

| EXAMINER<br>INITIAL |    | DOCUMENT NUMBER | DATE     | NAME              | CLASS | SUBCLASS | FILING DATE |
|---------------------|----|-----------------|----------|-------------------|-------|----------|-------------|
| /J.H./              | AA | 4,780,475       | 10/25/88 | Cerra et al.      |       |          |             |
|                     | AB | 4,906,664       | 3/6/90   | Bistrian et al.   |       |          |             |
|                     | AC | 5,514,656       | 5/7/96   | Cope et al.       |       |          |             |
|                     | AD | 5,547,927       | 8/20/03  | Cope et al.       |       |          |             |
|                     | AE | 5,700,782       | 12/23/97 | Cope et al.       |       |          |             |
|                     | AF | 5,827,896       | 10/27/98 | Ostlund et al.    |       |          |             |
|                     | AG | 5,985,339       | 11/16/99 | Kamarei           |       |          |             |
|                     | AH | 6,077,828       | 6/20/00  | Abbruzzese et al. |       |          |             |
|                     | AI | 6,232,346       | 5/15/01  | Sole et al.       |       |          |             |
|                     | AJ | 6,326,355       | 12/4/03  | Abbruzzese et al. |       |          |             |
|                     | AK | 6,387,883       | 5/14/02  | Abbruzzese e al.  |       |          |             |
|                     | AL |                 |          |                   |       |          |             |

## FOREIGN PATENT DOCUMENTS

|        |    | DOCUMENT NUMBER | DATE    | OFFICE                                  | CLASS | SUBCLASS | TRANSLATION              |                          |
|--------|----|-----------------|---------|---|-------|----------|--------------------------|--------------------------|
|        |    |                 |         |   |       |          | YES                      | NO                       |
| /J.H./ | AM | JP 11246435     | 9/14/99 | Japan (Derwent Abstract 1999-566489/78) |       |          | <input type="checkbox"/> | <input type="checkbox"/> |
|        | AN | WO00/21554      | 4/20/00 | PCT                                     |       |          | <input type="checkbox"/> | <input type="checkbox"/> |
|        | AO | WO89/08709      | 9/21/89 | PCT                                     |       |          | <input type="checkbox"/> | <input type="checkbox"/> |
|        | AP | WO97/13415      | 4/17/97 | PCT                                     |       |          | <input type="checkbox"/> | <input type="checkbox"/> |
|        | AQ | WO98/18751      | 5/7/98  | PCT                                     |       |          | <input type="checkbox"/> | <input type="checkbox"/> |

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent pages, Etc.)

|        |    |  |
|--------|----|--|
| /J.H./ | AR | "Omega-3-fatty acids used as an anti-cachexia agents - esp. in patients with tumors or AIDS, esp. used as fish oils added to low carbohydrate diet", (Derwent Abstract 90-225190/30).                |
| /J.H./ | AS | "Pharmaceutical compsns. contg. elcoss:penta:anoic acid or salt - for treating cancerous tumors, cachexia and to inhibit the llypolytic factor produced by tumors", (Derwent Abstract 90-292602/39). |
| /J.H./ | AT | Beck et al., "Anticachectic and Antitumor Effect of Eicosapentaenoic Acid and Its Effect on Protein Turnover", Cancer Research, Vol. 51, pp. 6089-6093, (November 15, 1991)                          |

EXAMINER

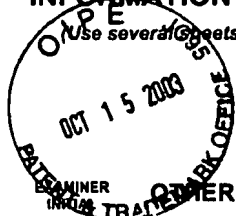
/Julie Ha/

DATE CONSIDERED

Oct. 15, 2003

\*EXAMINER: Initial of reference considered, whether or not citation is in conformance with MPEP 609: Draw a line through citation if not in conformance and not considered. Include a copy of this form with the next communication to applicant.

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EXAMINER INITIALS OTHER DOCUMENTS (Including Author, Title, Date, Pertinent pages, Etc.)

|        |    |  |
|--------|----|--|
| /J.H./ | DA | Biolo et al., "A New Model to Determine in Vivo the relationship Between Amino Acid Transmembrane Transport and Protein Kinetics in Muscle", Parenteral and Enteral Nutrition, Vol. 16, No. 4, pp. 305-315, (1992).  |
|        | DB | Biolo et al., "Protein synthesis and breakdown in skin and muscle: a leg model of amino acid kinetics", Am J Physiol., Vol. 26, No. 39, pp. E467-474, (1994).  |
|        | DC | Kemen et al., "Early postoperative enteral nutrition with arginine- $\omega$ -3 fatty acids and ribonucleic acid-supplemented diet versus placebo in cancer patients: An immunologic evaluation of Impact", Critical Care Medicine, Vol. 23, No. 4, (1995).    |
|        | DD | Senkal et al., "Modulation of Postoperative Immune Response by Enteral Nutrition with a Diet Enriched with Arginine, RNA, and Omega-3 Fatty Acids in Patients with Upper Gastrointestinal Cancer", Eur. J. Surg. Vol. 161, pp. 115-122, (1995).                |
|        | DE | Tera et al., "Compsn. for treating cachexia - contg. quinone or hydroquinine derivs. (Eng.), (Derwent Abstract 96-139442/14).  |
|        | DF | Tessitore et al, "Cancer Cachexia, Malnutrition, and Tissue Protein Turnover in Experimental Animals", Archives of Biochemistry and Biophysics, Vol. 306, No. 1, pp. 52-58, (October 1993).  |
|        | DG | Tisdale et al., "Inhibition of Weight Loss by $\omega$ -3 Fatty Acids in an Experimental Cachexia Model", Cancer Research, Vol. 50, pp. 5022-5026, (August 15, 1990).  |
|        | DH | Tisdale et al., "Inhibition of Tumour-Induced Lipolysis In Vitro And Cachexia And Tumour Growth In Vivo By Eicosapentaenoic Acid", Biochemical pharmacology, Vol.41, No. 1, pp. 103-107, (1991).   |
|        | DI | Tisdale M.J., "New lipid mobilizing agent used for treating obesity, and as diagnostic marker for cancer", (Derwent Abstract 2000-072831/06).  |
|        | DJ | Tisdale, M J, "Low mol. wt. lipolytic factor - obtd. from cachexia-inducing tumours or cultures, used as therapeutic agents for diagnosis or producing antibodies", (Derwent Abstract 89-292524/40).   |
|        | DK | Tisdale, M.J., Mechanism of Lipid Mobilization Associated with Cancer Cachexia: Interaction Between the Polyunsaturated Fatty Acid, Eicosapentaenoic Acid, and Inhibitory Guanine Nucleotide-Regulatory Protein", Prostaglandins Leukotrienes and Essential Fa |
| ↓      | DL | Wachtler et al., Influence of a pre-operative enteral supplement on functional activities of peripheral leukocytes from patiens with major surgery", Clinical Nutrition, Vol. 14, pp. 275-282, (1995).   |
|        | DM |  |
|        | DN |  |

EXAMINER

/Julie Ha/

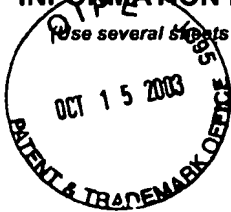
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September 15, 2003

Group

FOREIGN PATENT DOCUMENTS

| EXAMINER<br>INITIAL |    | DOCUMENT NUMBER | DATE    | OFFICE | CLASS | SUBCLASS | TRANSLATION              |                          |
|---------------------|----|-----------------|---------|--------|-------|----------|--------------------------|--------------------------|
|                     |    |                 |         |        |       |          | YES                      | NO                       |
| /J.H./              | CA | WO98/43617      | 10/8/98 | PCT    |       |          | <input type="checkbox"/> | <input type="checkbox"/> |
| /J.H./              | CB | WO99/40183      | 8/12/99 | PCT    |       |          | <input type="checkbox"/> | <input type="checkbox"/> |
|                     | CC |                 |         |        |       |          | <input type="checkbox"/> | <input type="checkbox"/> |
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|                     | CZ |                 |         |        |       |          | <input type="checkbox"/> | <input type="checkbox"/> |

EXAMINER /Julie Ha/ DATE CONSIDERED Oct. 15, 2003

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**INFORMATION DISCLOSURE CITATION**

(Use several sheets if necessary)



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10/662,678  
APPLICANT  
TROUP ET AL.  
FILING DATE  
SEPTEMBER 15, 2003

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1764

1654

**U.S. PATENT DOCUMENTS**

| EXAMINER<br>INITIAL | DOCUMENT NUMBER | DATE | NAME | CLASS | SUBCLASS | FILING DATE |
|---------------------|-----------------|------|------|-------|----------|-------------|
| AA                  |                 |      |      |       |          |             |
| AB                  |                 |      |      |       |          |             |
| AC                  |                 |      |      |       |          |             |
| AD                  |                 |      |      |       |          |             |
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| AH                  |                 |      |      |       |          |             |
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| AJ                  |                 |      |      |       |          |             |
| AK                  |                 |      |      |       |          |             |
| AL                  |                 |      |      |       |          |             |

**FOREIGN PATENT DOCUMENTS**

|        | DOCUMENT NUMBER | DATE    | OFFICE | CLASS | SUBCLASS | TRANSLATION              |                          |
|--------|-----------------|---------|--------|-------|----------|--------------------------|--------------------------|
|        |                 |         |        |       |          | YES                      | NO                       |
| /J.H./ | AM WO 02/087562 | 11/7/02 | PCT    |       |          | <input type="checkbox"/> | <input type="checkbox"/> |
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| AQ     |                 |         |        |       |          | <input type="checkbox"/> | <input type="checkbox"/> |

**OTHER DOCUMENTS** (Including Author, Title, Date, Pertinent pages, Etc.)

|    |  |
|----|--|
| AR |  |
| AS |  |
| AT |  |

EXAMINER /Julie Ha/ DATE CONSIDERED Jan 12, 2004

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|---------------------|----|-----------------|----------|------------------|-------|----------|-------------|
| /J.H./              | AA | 5,576,351       | 11/19/96 | Yoshimura et al. |       |          |             |
| /J.H./              | AB | 5,817,695       | 10/6/98  | Pellico          |       |          |             |
| /J.H./              | AC | 6,245,379       | 6/12/01  | Lepine           |       |          |             |
| /J.H./              | AD | 6,420,342       | 7/16/02  | Hageman et al.   |       |          |             |
|                     | AE |                 |          |                  |       |          |             |
|                     | AF |                 |          |                  |       |          |             |
|                     | AG |                 |          |                  |       |          |             |
|                     | AH |                 |          |                  |       |          |             |
|                     | AI |                 |          |                  |       |          |             |
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|                     | AL |                 |          |                  |       |          |             |

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|--|----|-----------------|------|--------|-------|----------|--------------------------|--------------------------|
|  |    |                 |      |        |       |          | YES                      | NO                       |
|  | AM |                 |      |        |       |          | <input type="checkbox"/> | <input type="checkbox"/> |
|  | AN |                 |      |        |       |          | <input type="checkbox"/> | <input type="checkbox"/> |
|  | AO |                 |      |        |       |          | <input type="checkbox"/> | <input type="checkbox"/> |
|  | AP |                 |      |        |       |          | <input type="checkbox"/> | <input type="checkbox"/> |
|  | AQ |                 |      |        |       |          | <input type="checkbox"/> | <input type="checkbox"/> |

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent pages, Etc.)

|        |    |  |
|--------|----|--|
| /J.H./ | AR | Derwent Abstracts - 90/020255, "Anti-cancer pharmaceutical compsns. - contain L-leucine, L-isoleucine, L-valine, L-lysine, L-threonine, L-tryptophan, L-methionine, L-cysteine", 12/05/89 (1989). [XP-002099910] |
| /J.H./ | AS | Ventrucci et al., "Effect of a leucine-supplemented diet on body composition changes in pregnant rats bearing Walker 256 tumor", Braz. J. Med. Biol. Res., Vol. 34, No. 3, pp. 333-338, (2001).                  |
| /J.H./ | AT | International Search Report  |

EXAMINER

/Julie Ha/

DATE CONSIDERED

Aug 10, 2004

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